Homeland Security
Science and Technology

TechNote

U.S. Department of Homeland Security
SAVER
System Assessment and Validation for Emergency Responders

The U.S. Department of Homeland Security (DHS) established the System Assessment and Validation for Emergency Responders (SAVER) Program to assist emergency responders making procurement decisions.

Located within the Science and Technology Directorate (S&T) of DHS, the SAVER Program conducts objective assessments and validations on commercial equipment and systems and provides those results along with other relevant equipment information to the emergency response community in an operationally useful form. SAVER provides information on equipment that falls within the categories listed in the DHS Authorized Equipment List (AEL).

The SAVER Program is supported by a network of technical agents who perform assessment and validation activities. Further, SAVER focuses primarily on two main questions for the emergency responder community: "What equipment is available?" and "How does it perform?"

For more information on this and other technologies, contact the SAVER Program Support Office.

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This SAVER TechNote was prepared by the National Urban Security Technology Laboratory for the SAVER Program.

NUSTL

Biological Agent Detection Equipment for First Responders' Field Use

Biological Agents (BAs) have been historically used as weapons of terror. In 2001, the United States suffered through an intentional dispersal of anthrax spores via envelopes mailed to high-profile targets. This attack renewed attention to the potential threat that BAs and toxins pose. BAs have the ability to multiply inside the human body and can be transmitted from person-to-person. Additionally, in the absence of adequate detection equipment, there is a time lag during the incubation period between infection and the appearance of symptoms. In order to be able to contain an outbreak, first responders and health professionals need early detection of BAs. BA field kits and assays need to exhibit sufficient sensitivity and specificity to alert first responders to the potential presence of a BA, give quick results, and be easy to use.

Biological Agents as Weapons

Biological Agents (BAs) are living organisms, or materials derived from them, that can be weaponized to cause disease or death in humans, animals, and plants. The main classes of BAs that could be used in a terrorist attack are naturally occurring viruses and bacteria that can be readily obtained from soil, water, and clinical and research laboratories, and which can be easily and inexpensively produced. Toxins, poisonous substances produced within living cells or organisms, can also be weaponized and are also categorized as BAs.

Naturally occurring bacteria and toxins can be genetically altered, synthetically manufactured, and produced in a laboratory environment to increase their concentration and effectiveness when disseminated. Viral agents are harder to cultivate but are high risk BAs because many do not respond to antibiotics, and symptoms may not appear until a long time after dissemination, making it harder to trace back to the culprit and limit the spread of contagion.

BAs can reproduce and spread quickly in target populations in very low concentrations compared to chemical agents. The Centers for Disease Control and Prevention classifies potential BAs by how easily they can be disseminated and their associated mortality rates. The three high-priority categories for BAs are:

- *Category A:* Easily disseminated or transmitted from person-to person, with high mortality rates–includes anthrax, smallpox, botulism, plague, tularemia, and viral hemorrhagic fevers.
- *Category B:* Moderately easy to disseminate, with moderate morbidity and low mortality rates–includes brucellosis, salmonella, meliodosis, typhus fever, ricin toxin, etc.
- *Category C:* Emerging pathogens that can be engineered for mass

dissemination in the future because of availability, ease of production/dissemination, potential for high morbidity and mortality rates, and which pose major public health problems–includes viruses for hemorrhagic fever, encephalitis, influenza, etc.

Biological Agent Detection Equipment–Field Kits and Assays

The utility of BA detection equipment to first responders will depend on the characteristics of the detection equipment, the type and quantity of BAs to be detected, the environment in which the sampling takes place, training, and the objective of the emergency first responder unit. Therefore, at a minimum, field kits and assays should be able to discriminate BAs from harmless biological and nonbiological material present in the environment or the sample. They must also be easy to use and give a fast positive or negative response.

Field kits assist first responders in the initial risk assessment phase of a potential BA attack and provide support for short-term tactical decisions, such as securing a building and denying re-occupancy, holding first responders and hazardous material (HazMat) teams on the scene, prioritizing the transport and testing of samples at a Laboratory Response Network (LRN) facility, accounting for potentially exposed individuals, and providing public-health officials and public-policy makers with knowledge of the increased potential of a credible event. These field kits and assays are not meant to identify the BA. Test results obtained from field kits and assays are presumptive and require a confirmatory process, usually through the LRN or other public-health laboratory, where a range of techniques can be used to increase accuracy. These methods are quite definitive, but a high-certainty characterization of a pathogen can take two or more working days.

Current field kits for bulk (visible) material sampling provide tools to do some or all of the following: a) protein kits that test for the presence of protein as an indicator of a possible BA, but are not specific to bacteria or biothreat agents; b) pH measurements to determine if the substance is acidic, basic, or neutral; c) spore detectors that identify the presence of any and all spores, but are not specific to a spore-forming biothreat agent; d) metabolic assays that detect enzymes such as catalase to indicate the presence of bacteria, but are not specific to biothreat agents; e) immunoassays such as handheld assays (HHAs) that detect target antigens specific to biothreat agents; and f) molecular assays that detect biothreat agent DNA, some of which may be multiplexed to detect more than one biothreat agent at a time.

The false-positive and false-negative rates of field kits and assays under ideal laboratory conditions are a few percent or better for test samples, but for real-world samples they can be worse due to contamination (e.g., with environmental residues) of the sample. A more expensive capability than HHAs that many first responders now have, are field-portable, real-time polymerase chain reaction (PCR) instruments. PCR allows for the amplification of nucleic acids in the sample, providing a higher "signal" to detect the presence of BAs. In contrast to standard PCR that requires post-processing, real-time PCR uses fluorescent markers to detect and quantify the nucleic acid amplification product as it is being produced. Reports indicate that the false-positive rate for real-time PCR in the field is quite low, but that the false-negative rate can be higher due to PCR inhibition caused by environmental contaminants. PCR vendors typically recommend some type of sample preparation to minimize false negatives, but further improvements are still needed. These machines also require a higher level of expertise by first responders to operate efficiently in the field.

Over the last 20 years, faster, more compact versions of immunoassays, PCR analysis, and mass spectrometry have migrated to the field, where some are now used as second- or third-stage identifiers. However, the confirmation of a BA can only be achieved through the use of cultural, biochemical, or molecular methods, or by sensitive immunoassays which can only be done through the LRN or other qualified laboratories.

Public health preparedness programs seek to define thresholds at which results become "actionable," i.e., when interventions must be implemented to reduce the impact of a presumed attack. First responders are the first line of defense against such an attack, and therefore, the need for efficient and accurate BA detection field kits and assays is essential.

References and Resources

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